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| 10/519,580 | 07/11/2005 | Syed V.S. Kashmiri | 4239-66176-05 | 3640 |
| 36218 7590 08/24/2007 KLARQUIST SPARKMAN, LLP 121 S.W. SALMON STREET SUITE #1600 PORTLAND, OR 97204-2988 | | | EXAMINER TUNGATURTHI, PARITHOSH K | |
| | | | ART UNIT 1643 | PAPER NUMBER |
| | | | MAIL DATE 08/24/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1-4,6,8,10-12,16,20-28,32-35,44,45,47,48,52,56 and 67.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature recited in claim 1 is a humanized CC49 antibody wherein a LCDR3 of the humanized CC49 antibody of a functional fragment comprises a non-conservative amino acid substitution. In regard to this, Iwahashi et al (Molecular Immunology, 1999, 36:1079-1091) in view of Pastan et al (U.S. Patent 7081518; 05/26/2000) read on the claim. Iwahashi et al teach humanized monoclonal CC49 antibodies and Pastan et al teach antibodies with substitutions in the CDR3 of the light chain having higher binding affinity than the parent antibody. Therefore the technical feature recited in claim 1 is not special. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 1-4, 6, 8, 10-12, 16, 20, 23-28, 52, 56 and 67, drawn to a humanized CC49 antibody, wherein a L-CDR3 of the humanized CC49 antibody or of a functional fragment of the humanized CC49 antibody comprises a non-conservative amino acid substitution.

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- II. Claims 21 and 22 drawn to a nucleic acid molecule and a vector comprising such nucleic acid molecule.
- III. Claims 32-35, drawn to a method of detecting a TAG-72-expressing tumor in a subject, comprising contacting a sample from the subject in vivo or in vitro with the antibody.
- IV. Claims 44, 45, 47 and 48, drawn to a method of treating a subject having a tumor that expresses TAG-72, comprising administering to the subject a therapeutically effective amount of the antibody.

2. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above, in view of the teaching of Thompson et al the groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature of claim 1 is not special.

Inventions of Groups I and II represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. The polynucleic acid of Group II and the antibody of Group I are structurally and chemically different from each other. The polynucleotide is made by nucleic acid synthesis and the antibody is raised by immunization. Furthermore, the polynucleotide can be used for hybridization screening and the antibody can be used to immunopurify the polypeptide, for example. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions I, II and III are patentably distinct.

The inventions of Groups III and IV are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. In the instant case, Group III recites a method of detecting a TAG-72-expressing tumor in a subject, comprising: contacting a sample from the subject in vivo or in vitro with the antibody and Group IV recites a method of treating a subject having a tumor that expresses TAG-72, comprising administering to the subject a therapeutically effective amount of the antibody. Thus, each group differs in method objectives, method steps and parameters and in the reagents used. Further, each group is unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has different mode of operation. Each invention further performs this function using structurally and functionally divergent material. Moreover, the methodology and materials necessary for detection differ significantly for each of the materials. The examination of all groups would require different searches in the U.S. PATENT shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions III and IV are separate and distinct in having different method steps and different endpoints and are patentably distinct.

The inventions of Group I and the method of Groups III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In

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the instant case the antibody product as claimed can be used in a materially different process such as affinity chromatography in addition to the materially different methods of Groups III and IV.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

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Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parithosh K. Tungaturthi whose telephone number is

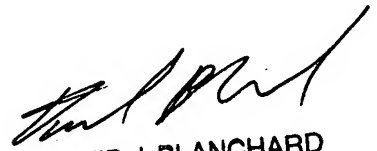
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571-272-8789. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Parithosh K. Tungaturthi
Ph: (571) 272-8789


DAVID J. BLANCHARD
PATENT EXAMINER
PRIMARY